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Kathy Ashton
Name

Kathy Ashton
Signature

December 17, 2007
Date of Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Rustum et al.

Examiner: Frederick F. Krass

Serial No.: 10/663,109

Art Unit: 1614

Filed: September 15, 2003

For: Method of Reducing Alopecia and Bladder Toxicity of Cyclophosphamide

37 C.F.R. 1.132 Declaration

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Dr. Youcef M. Rustum, declare:

1. That I am a Professor and Chairperson of the Department of Cancer Biology at Roswell Park Cancer Institute of Buffalo, New York, that I am an inventor on the patent application referenced above, and that I have been researching pharmacology and cancer for over forty years.
2. That I am familiar with the Office Action of July 16, 2007, for this application.
3. That alopecia is a predictable side effect that is known to regularly occur with cyclophosphamide treatment. For example, the enclosed reference of Cline (Cancer Nursing (June, 1984 p221 - 228) establishes that it is known that alopecia is a common side effect of cyclophosphamide administration, and that "severe alopecia occurs in 75-90% of patients receiving intravenous cyclophosphamide" (p221, right column, last full paragraph). Additionally, the enclosed reference of Seipp (Cancer Principles & Practice of Oncology, (1977) Vol. 2, 5th Edition, Devitta, Jr., Hellman & Rosenberg Editors, p. 2757-2758) describes hair loss as common after two cycles of

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cyclophosphamide above 500 mg/m² (p2757, left column, last full paragraph). Therefore, cyclophosphamide is known to predictably cause alopecia at recognized chemotherapeutic doses.

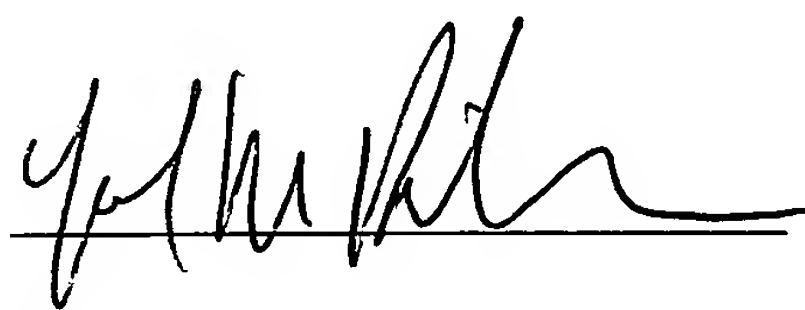
4. That the enclosed reference of Fakih et al. (Cancer Chemother Pharmacol. (2007 Nov 8) [Epub ahead of print]) on which I am an author describes a phase I study to determine recommended doses of selenomethionine (SLM) that consistently result in protective plasma selenium concentrations (see Abstract). Therefore, since the protective effect of selenium on cyclophosphamide-induced alopecia has now been discovered, optimizing the dosage of selenium containing compounds can be routinely performed by clinicians.

4 That all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 101 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued there from.

Respectfully submitted,

12/7/07

Date



Dr. Youcef M. Rustum